

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	)	
Stenland, <i>et al.</i>	)	Examiner: Horning, M.
Serial No.: 10/659,789	)	Art Unit: 1645
Filed: September 10, 2003	)	Attorney Doc. No. MSC 8015
For: Prion Clearance Using Particulate	)	(B185 1210.1)
Metal Oxides	)	Confirmation No. 5573

Declaration Under 37 CFR § 1.131

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

I, Jarrett C. Terry, residing at 9916 Miranda Drive, Raleigh, NC 27617, state as follows:

1. I am one of the applicants in the above-identified patent application and a joint inventor of the subject matter claimed in the application.
2. The invention claimed in the above-identified application was conceived and reduced to practice prior to April 4, 2003, the effective date of *Carbonell, et al.*, as evidenced by the attached *Exhibits 1* and *2*. Both *Exhibits* are copies of notebook pages that were signed, witnessed, and dated prior to April 4, 2003 (actual dates redacted). *Exhibit 1* shows experiments wherein 1) a filtrate comprising biological material was spiked with scrapie brain homogenate (SBH; rodent-adapted sheep scrapie brain homogenate, a source of prion protein), 2) the solution was contacted with Cab-O-Sil (a fumed silica filter aid produced by Cabot Corporation), and 3) a resulting solution was separated from the Cab-O-Sil filter aid. The gels shown depict substantial clearance of prion protein via contact with fumed silica following its removal from the solution. *Exhibit 2* shows similar clearance experiments using SBH-spiked samples and subsequent contact of the test

solution with aluminum hydroxide ( $\text{Al}(\text{OH})_3$ ). Again, a substantial clearance of prion protein was noted.

3. The Exhibits show that adding a metal oxide, e.g., fumed silica or aluminum hydroxide, to a biological material to obtain a solution comprising a mixture of the metal oxide and the biological material and separating the metal oxide from the mixture to form a resulting solution results in a substantial reduction of pathogenic prion proteins possibly contaminating the biological material. Accordingly, the claimed invention was conceived and reduced to practice prior to April 4, 2003.

I hereby declare that all statements made herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of this application or any patent issued thereon.

3/18/08  
Date

Jarrett C. Terry  
Jarrett C. Terry

## BAYER CORPORATION

SUBJECT Ab-O-Sil Filtration Study

Purpose: Proof of principle to determine if Ab-O-Sil can remove PEP  
 Spore in a culture broth.

Methods: 200 ml of the filtrate generated on p. 61 of this book was  
 spiked with 100 µl of Chalk Spill.  
 100 µl Ab-O-Sil was dissolved into 10 ml of 2M KOH (Barnstead)  
 and 1 ml of the resulting suspension was pushed across the  
 membrane in the stack for each 100 ml.  
 4 ml of the Spill Spikes filtrate were removed as a "Pre-Test" sample.  
 Syringe filters attached to the end of flask with Ab-O-Sil were  
 also sampled with this study to determine if removal by the filter  
 without Ab-O-Sil.

4 ml of distilled water spiked solution was passed over a 0.22 µm  
 Millex filter both with and without Ab-O-Sil and a 0.22 µm Millex  
 filter with and without Ab-O-Sil. The clearance results are as  
 follows:



SIGNED BY James M. Bond DATE 10/1/77  
 WITNESSED AND UNDERTOOK BY [Redacted] DATE [Redacted]  
 CROSS REFERENCES

## BAYER CORPORATION

SUBJECT Oral Solution p. 63

Purpose: Proof of principle to determine if Ab-O-Sil can remove PEP  
 Spore in a culture broth.

Methods: 200 ml of the filtrate generated on p. 61 of this book was  
 spiked with 100 µl of Chalk Spill.  
 100 µl Ab-O-Sil was dissolved into 10 ml of 2M KOH (Barnstead)  
 and 1 ml of the resulting suspension was pushed across the  
 membrane in the stack for each 100 ml.  
 4 ml of the Spill Spikes filtrate were removed as a "Pre-Test" sample.  
 Syringe filters attached to the end of flask with Ab-O-Sil were  
 also sampled with this study to determine if removal by the filter  
 without Ab-O-Sil.

Results: 200 ml of the filtrate  
 spiked with 100 µl of Chalk Spill  
 was passed over a 0.22 µm  
 Millex filter both with and without Ab-O-Sil and a 0.22 µm Millex  
 filter with and without Ab-O-Sil. The clearance results are as  
 follows:



SIGNED BY James M. Bond DATE 10/1/77  
 WITNESSED AND UNDERTOOK BY [Redacted] DATE [Redacted]  
 CROSS REFERENCES

## BAYER CORPORATION

SUBJECT 155 Corporation 3M BEE, Albany

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34

155 Corporation 3M BEE, Albany, New York



155 Corporation 3M BEE, Albany, New York



Result:

Five to six lbs of debris were visible in the pond and water table.  
4-22 lbs were visible in the pit.  
In the past this step has yielded 3-4 lbs of debris in the vicinity.

The "Main Ponds" clearance group had reported that 3000 lbs of debris were in the pond. 14, 785/1983 well tracking with 30% PDS (Mead) yielded 2400 lbs of debris with regard to the pit.

We decided to use a 155 gallon in 1983 to try to decontaminate the same level of debris.

Prepared the equipment - 155 gal used. Removal of debris was not achieved to 16 mt. While 18 lbs of debris were yielded with 2400 lbs of debris. PDS (Mead) yielded 2400 lbs of debris.

SIGNED BY James J. [Signature] DATE [Redacted]  
 WITNESSED BY [Redacted] DATE [Redacted]  
 CROSS REFERENCES:

## BAYER CORPORATION

SUBJECT 155 Corporation (Cont'd)

155 Corporation 3M BEE, Albany, New York



These results raise the question: Does the 155 gal. debris level to the eye material and debris with 155 gal. debris in the vicinity of the debris? spoke in debris in the vicinity of the debris?

4-22 lbs of debris in the pit.

SIGNED BY James J. [Signature] DATE [Redacted]  
 WITNESSED BY [Redacted] DATE [Redacted]  
 CROSS REFERENCES: